#### FACSIMILE COVER SHEET

## SALIWANCHIK, LLOYD & SALIWANCHIK

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**EXAMINER:** Not yet assigned

FROM: Margaret Efron

COMPANY:

U.S. Patent Office

**DATE:** January 26, 2006

FAX NO.:

Art Unit 1645 (571) 273-8300

NO. OF PAGES

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18

#### SUBJECT/MESSAGE:

Re:

Serial No. 10/535,585; filed May 18, 2005

Docket No. SPO-121

- Request for Correction of Filing Receipt and Request for Correction of Notice of Acceptance (3 pages);
- 2) Marked-up copy of corrected Filing Receipt (3 pages);
- 3) Marked-up copy of Notice of Acceptance (2 pages)
- 4) Copy of executed Declaration and Power of Attorney (3 pages); and
- 5) Copy of Preliminary Amendment (6 pages).

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## RECEIVED CENTRAL FAX CENTER

JAN 26 2006

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on the date shown below:

Janvary 26, 2006

David R. Saliwanchik, Patent Attorney

Patent Application Docket No. SPO-121 Serial No.10/535,585 Conf. No. 7558

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

Kisac Kume et al.

Scrial No.

10/535,585

Filed

May 18, 2005

Art Unit.

1645

For

Nutritional Compositions

Office of Initial Patent Examination's Filing Receipt Corrections Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# REQUEST FOR CORRECTION OF FILING RECEIPT & REQUEST FOR CORRECTION OF NOTICE OF ACCEPTANCE

Sir:

The applicants respectfully request the correction of errors in the Official Filing Receipt and Notice of Acceptance for the above-identified patent application. The corrections needed are as follows:

Foreign Applications

JAPAN 2002-339948 11/21/2003

Should read

JAPAN 2002-339948 11/22/2002

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Docket No. SPO-121 Serial No. 10/535,585

IND CLMS

2

Should read

IND CLMS

3

Please note that claims 1, 9 and 17 are independent claims. The claims pending in the subject application are the claims listed in the Preliminary Amendment that was submitted with the subject application for filing on May 18, 2005.

The Notice of Acceptance of Application under 35 U.S.C. 371 and 37 Ct/R 1.495 indicates that the U.S. Receiving Office received Biochemical Sequence Listing filed on May 18, 2005. Applicants note that the subject application does not include a sequence listing and that no sequence listing was filed with the subject application. Applicants respectfully request a corrected Notice of Acceptance of Application indicating no sequence listing.

The applicants are attaching herewith copies of the executed Declaration and Power of Attorney form as well as a copy of the Preliminary Amendment. Also marked-up copies of the Official Filing Receipt and Notice of Acceptance that indicate the corrections needed accompanies this Request. Correction of the above is respectfully requested.

Docket No. SPO-121 Serial No. 10/535,585

The Commissioner is hereby authorized to charge any fees under 37 C.F.R.§§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Respectfully submitted,

David R. Saliwanchik

Patent Attorney

Registration No. 31,794

Phone No.:

352-375-8100

Address:

P.O. Box 142950

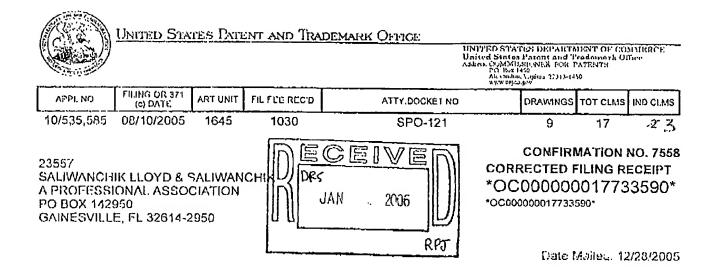
Gainesville, FL 32614-2950

DRS/la

Attachments: Copy of marked-up version of Filing Receipt;

Copy of marked-up version of Notice of Acceptance of Application

Copy of executed Declaration; and Copy of Preliminary Amendment



Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

#### Applicant(s)

Hisac Kurne, Kanagawa, JAPAN; Makoto Yamaguchi, Kanagawa, JAPAN; Kenji Mizurnoto, Kanagawa, JAPAN; Hajime Sasaki, Kanagawa, JAPAN;

Power of Attorney: The patent practitioners associated with Customer Number 23557.

#### Domestic Priority data as claimed by applicant

This application is a 371 of PCT/JP03/14918 11/21/2003

Foreign Applications

27-

JAPAN 2002-339948 11/24/2002

If Required, Foreign Filing License Granted: 12/28/2005

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US10/535,585

Projected Publication Date: 04/06/2006

Non-Publication Request: No

Early Publication Request: No

Title

Nutritional compositions

Preliminary Class

424

## PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process simplifies the filing of patent applications on the same invention in member countries, but does not result in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Palents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4 i 58).

LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

#### GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted

#### under 37 CFR 5.13 or 5.14

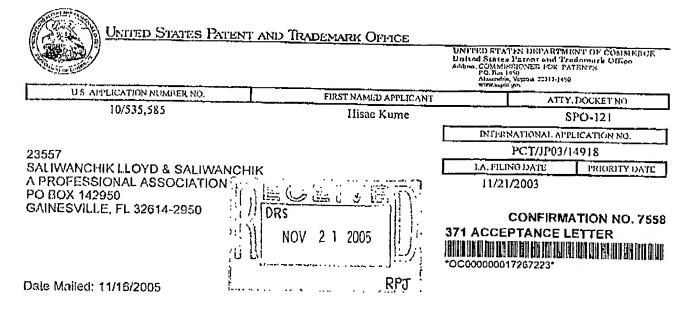
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The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

#### NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

Page 1 of 2



## NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has niet the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

08/10/2005 DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS

08/10/2005

DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE. The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Copy of the International Application filed on 05/18/2005
- Copy of the International Search Report filed on 05/18/2005
- Copy of IPE Report filed on 05/18/2005
- Preliminary Amendments filed on 05/18/2005
- Oath or Declaration filed on 08/10/2005
- NO Soquence disting \* Biochemical Sequence-Listing filed on 05/48/2005 -
- Request for Immediate Examination filed on 05/18/2005
- Copy of references cited in ISR filed on 05/18/2005
- U.S. Basic National Fees filed on 05/18/2005
- Priority Documents filed on 05/18/2005

Page 2 of 2

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

MAMIE P PERSON Telephone: (703) 308-9140 EXT 227

PART 1 - ATTORNEY/APPLICANT COPY

FORM PCT/DO/EO/903 (371 Acceptance Notice)

Docket No. SPO-121

#### DECLARATION (37 C.F.R. § 1.63) AND POWER OF ATTORNEY

As a below-named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name; and

I believe that I am the original, first, and sole inventor (if only one name is listed below), or an original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **Nutritional Compositions**, specification for which

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I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (a).

I hereby claim foreign priority benefits under Title 35, United States Code §119 and/or §365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Application	Country	Filing Date	Priority
Serial No.			Claimed
2002-339948	JP	November 22, 2002	Yes

I hereby claim priority benefits under Title 35, United States Code §119 of any provisional application(s) for patent listed below:

Application Filing Date Priority Claimed Serial No.

I hereby claim the benefit under Title 35, United States Code, §120 and/or §365 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which became available between the filing date of the prior application and the national or PCI international filing date of this application:

Application	Filing Date	Status (Patented,
Serial No.		Pending, Abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint the following persons registered to practice before the Patent and Trademark Office as my intorneys with full power of substitution and revocation to prosecute this application and all divisions and continuations thereof and to transact all business in the Patent and Trademark Office connected therewith who are associated with Costomer Number 23557.

Docket No. SPO-121

The attorneys/patent agents currently associated with this Customer Number are: David R. Saliwanchik, Reg. No. 31,794; Jeff Lloyd, Reg. No. 35,589; Doran R. Pace, Reg. No. 38,261; Jay M. Sanders, Reg. No. 39,355; Jean Kyle, Reg. No. 36,987; James S. Parker, Reg. No. 40,119; Frank C. Eisenschenk, Reg. No. 45,332; Glenn P. Ladwig, Reg. No. 46,853; Margaret Efron, Reg. No. 47,545; Gwendolyn L. Daniels, Reg. No. 51,594; John M. Sanders, Reg. No. 30,126; Jenna M. Morrison, Reg. No. 55,468; and Mai-Tram Dinh Lauer, Reg. No. 43,589.

I request that all correspondence be sent to:

David R. Saliwanchik
Saliwanchik, Lloyd & Saliwanchik
A Professional Association
PO Box 142950
Gainesville, FL 32614-2950
I further request that all telephone communications be directed to:

David R. Saliwanchik 352-375-8100

Docket No. SPO-121

Name of First or Sole Inventor Hisae Kume				
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540, Naruda, Odawara-shi, Kanagawa 250-0862 Japan				
Signature of First or Sole Inventor  Date June 27, 2005				
Name of Second Joint Inventor Makoto Yamaguchi				
Residence Kanagawa, Japan Citizenship Japan				
C/O NUTRITION SCIENCE INSTITUTE, Post Office Address MEIJI DAIRIES CORPORATION,				
540, Naruda, Odawara-shi, Kanagawa 250-0862 Japan				
Makote Jamegachi Date June 27, 2005 Signaturu of Second Joint Inventor				
Constitute of Occasio Joint Inventor				
Name of Third Joint Inventor Kenji Mizumoto				
Residence Kanagawa, Japan Citizenship Japan				
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540, Naruda, Odawara-shi, Kanagawa 250-0862 Japan				
Signature of Third Joint Inventor  Date  June 27, 20015				
Signature of Hurd Joint Inventor				
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Post Office Address MEII DAIRIES CORPORATION,				
540, Naruda, Odawara-shi, Kanagawa 250-0862 Japan				
Hajim Baadi Date June 27, 2005				
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May 18, 2005

Patent Application Preliminary Amendment Docket No. SPO-121

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

JAN 26 2006

Applicant(s) :

Hisae Kume; Makoto Yamaguchi; Kenji Mizumoto; Hajime Sasaki

Docket No.

SPO-121

For

**Nutritional Compositions** 

Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

:

#### PRELIMINARY AMENDMENT

This application is a National Stage Application of International Application Number PCT/JP2003/014918. Please amend the above-identified patent application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims beginning on page 3 of this paper.

Remarks follow the amendment sections of this paper.

Docket No. SPO-121

#### In the Specification

Please add the following paragraph at page 1, above line 2 after the Title:

This application is a National Stage Application of International Application Number PCTVJP2003/014918, filed November 21, 2003; which claims priority to Japanese Application No. 2002-339948, filed November 22, 2002.

Dockei No. SPO-121

#### In the claims

The following amendments are made with respect to the claims in the International application PCT/JP2003/014918.

This listing of claims will replace all prior versions and listings of claims in this application.

#### Claims

- I (Original). A nutritional composition for liver disease patients comprising: a milk protein hydrolysate and a protein derived from fermented milk as proteins; a high oleic acid-containing oil and milk lecithin and/or soybean lecithin as lipids; and palatinose as a carbohydrate.
- 2 (Original). The mutritional composition according to claim 1, wherein said milk protein is selected from the group consisting of easein, a milk protein concentrate (MPC), a whey protein concentrate (WPC), a whey protein isolate (WPI), α-lactoalburnin, β-lactoglobulin, and lactoferrin.
- 3 (Original). The nutritional composition according to claim 1, wherein said fermented milk-derived protein is from a composition in which the whey in fermented milk has been reduced.
- 4 (Original). The nutritional composition according to claim 1, wherein said fermented milk-derived protein is from fresh cheese.
- 5 (Original). The nutritional composition according to claim 4, wherein said fresh cheese is quark.
- 6 (Original). The nutritional composition according to claim 1, wherein said milk protein hydrolysate may be obtained by hydrolyzing a whey protein isolate (WPI) with alkalase from Bacillus licheniformus, and trypsin from a porcine pancreas.

Docket No. SPO-121

- 7 (Original). The nutritional composition according to claim 6, which is a permeate obtained by further treatment with an ultrafiltration membrane having a fractionation molecular weight of 10,000.
- 8 (Original). The nutritional composition according to claim 7, wherein the chromatogram from reverse phase HPLC separation is shown in Fig. 1.
- 9 (Original). A nutritional composition for patients under high levels of invasive stress, wherein said nutritional composition comprises: a milk protein hydrolysate and a protein derived from fermented milk as proteins; a high oleic acid-containing oil and milk lecithin and/or soybean lecithin as lipids; and palatinose as a carbohydrate.
- 10 (Original). The nutritional composition according to claim 9, wherein said milk protein is selected from the group consisting of casein, a milk protein concentrate (MPC), a whey protein concentrate (WPC), a whey protein isolate (WPI), α-lactoalbumin, β-lactoglobulin, and lactoferrin.
- 11 (Original). The nutritional composition according to claim 9, wherein said fermented milk-derived protein is from a composition in which the whey in the fermented milk has been reduced.
- 12 (Original). The nutritional composition according to claim 9, wherein said fernanted milk-derived protein is from fresh cheese.
- 13 (Original). The nutritional composition according to claim 12, wherein said fresh cheese is quark.
- 14 (Original). The nutritional composition according to claim 9, wherein said milk protein hydrolysate may be obtained by hydrolyzing a whey protein isolate (WPI) with alkalase derived from *Bacillus licheniformus*, and trypsin from a porcine pancreas.
- 15 (Original). The nutritional composition according to claim 14, which is a permeate obtained by further treatment with an ultrafiltration membrane having a fractionation molecular weight of 10,000.

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Docket No. SPO-121

16 (Original). The nutritional composition according to claim 15, wherein the chromatogram from reverse phase HPLC separation is shown in Fig. 1.

17 (New). A method for providing nutrition to a patient having liver disease and/or a high level of invasive stress, wherein said method comprises administering, to such a patient, a nutritional composition that comprises:

a milk protein hydrolysate and a protein derived from fermented milk as proteins; a high oleic acid-containing oil and milk lecithin and/or soybean lecithin as lipids; and palatinose as a carbohydrate.

Docket No. SPO-121

#### Remarks

This application is a National Stage Application of International Application Number PCTX/P2003/014918. By this amendment, the subject specification has been amended to include a cross-reference to a related application section.

Claims 1-16 were pending in the international patent application. By this Amendment, the applicants have added new claim 17. Accordingly, claims 1-17 are pending in the subject application. No new matter has been added by this Amendment.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§§1.16, 1.17, or 1.492 as required by this paper to Deposit Account No. 19-0065.

Respectfully Submitted,

David R. Saliwanchik

Patent Attorney

Registration No. 31,794

Phone No.:

352-375-8100

Address:

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DRS/hcy